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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,030	12/12/2003	Vahid C. Saadat	USGINZ02513	3503
40518 7590 02/27/2007 LEVINE BAGADE HAN LLP 2483 EAST BAYSHORE ROAD, SUITE 100 PALO ALTO, CA 94303			EXAMINER KOTINI, PAVITRA	
			ART UNIT 3731	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/735,030

Applicant(s)

SAADAT ET AL.

Examiner

Pavitra Kotini

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/8/05, 1/4/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election **without** traverse of Group III, claims 26-30, in the reply filed on 2/2/07 is acknowledged. Claims 1-25 have been cancelled and new claims 31-44 have been added. Accordingly, claims 26-44 are presently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the limitation of the flexible delivery catheter to buckle into transverse alignment with the tissue fold is not disclosed in the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Silverstein et al. (US-5025778).

Silverstein discloses an apparatus for performing a medical procedure within a hollow body organ comprising:

Regarding **claim 26**, an overtube (34) having a flexible state that facilitates insertion of the overtube into the hollow body organ (col.2, lines 35-37), and a rigid state wherein the overtube resists bending forces exerted on the overtube (col.2, lines 40-43); and a mechanism selectively operable to reversibly transition the overtube between the flexible and rigid states, wherein at least a portion of the overtube is configured to be manipulated from outside the hollow body organ (col.3, lines 1-12).

Regarding **claim 27**, wherein at least one section of the overtube is adapted to remain in the flexible state upon transition of the overtube to the rigid state (col.3, lines 9-12).

Regarding **claim 28**, wherein at least one section of the overtube comprises varied rigidity relative to a different section of the overtube when the overtube is disposed in the rigid state (col.3, lines 1-12).

Regarding **claim 29**, wherein at least one section of the overtube comprises varied flexibility relative to a different section of the overtube when the overtube is disposed in the flexible state (col.3, lines 1-12)

Regarding **claim 30**, wherein at least one section of the overtube comprises is steerable (col.8, lines 35-40).

Regarding **claim 31**, a catheter (54) having a flexible tube with a distal region configured for insertion through the overtube and into the hollow body organ (fig.24); and a tissue engaging assembly disposed on the distal region (fig. 13, 144), the tissue engaging assembly defining a first tissue contact point (one of the fingers of grasper 144 or 106).

Regarding **claim 32**, a second tissue contact point disposed at a location initially proximal of, or in line with, the first tissue contact point (figs. 13-16, second finger of grasper 114 or 106).

Regarding **claim 33**, a tissue approximation device for moving the first tissue contact point to a position proximal of the second tissue contact point to form a tissue fold (fig. 15).

Regarding **claim 34**, a third tissue contact point disposed at a location initially proximal of, or in line with, the first tissue contact point (fig. 14 or 16), wherein the tissue approximation device for moving moves the first tissue contact point to a position proximal of the third tissue contact point to form the tissue fold, so that the second and third tissue contact points are disposed on opposing sides of the tissue fold (fig. 15).

Regarding **claim 35**, wherein the tissue approximation device for moving linearly displaces the first tissue contact point relative to the second and third tissue contact points (fig. 15, col.9, lines 42-50).

Regarding **claim 36**, an anchor delivery system adapted to deliver an anchor assembly and secure a tissue fold (fig. 15, 148).

Regarding **claim 37**, wherein the anchor delivery system comprises a flexible delivery catheter adapted for insertion into the hollow body organ (fig. 15).

Regarding **claim 38**, the flexible delivery catheter is configured to buckle into transverse alignment with the tissue fold (fig. 15).

Regarding **claim 39**, wherein the anchor delivery system further comprises a needle configured for advancement through the flexible delivery catheter and for transverse passage through the tissue fold (fig. 15).

Regarding **claim 40**, it is old and well known that the anchor assembly (i.e. suture) can be configured for delivery through the needle (col.9, lines 51-52 disclose a medical device for performing a medical procedure; fig. 15 shows a needle like apparatus through which a suture can be configured to delivery through the needle).

Regarding **claims 41-43**, the tissue engaging assembly (144) is capable of engaging either the mucosa, muscularis, or serosa, and thereby defining the first tissue contact point.

Regarding **claim 44**, wherein the tissue fold is capable of being serosa-to-serosa tissue contact and the anchor assembly is adapted to secure the serosa-to-serosa tissue contact (fig. 15).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 26 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 10/734562. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are broader than the claims of the above stated co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 26 is also rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19, 20, 39 of U.S. Patent No. 6960163. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims are broader in some respects and adds features in other respects.

Claim 26 recites, an overtube having a flexible state that facilitates insertion of the overtube into the hollow body organ and a rigid state wherein the overtube resists bending forces exerted on the overtube (see claim 19 of the patent); and a mechanism

selectively operable to reversibly transition the overtube between the flexible and rigid states (see claim 20 of the patent), wherein at least a portion of the overtube is configured to be manipulated from outside the hollow body organ (see claim 39 of the patent).

Claim 26 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6942613. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are broader than the claims of the patent.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chang (US-5941815) and Bauerfeind et al. (US-5337733) disclose an overtube having varying flexibility and rigidity; Schurr (US-20020082621) discloses a device and method for folding and securing tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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2/20/07


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
